

PAIN RELEASE- menthol oil
Saje Natural Business Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pain Release Oil Blend (30 ml, 10 ml, 6 ml)

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS PACKAGE FOR FULL INFORMATION.

DRUG FACTS

Active ingredient

Menthol 1.98%

Purpose Topical Analgesic

Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.

Warnings

For external use only.

Flammable: Keep away from fire or flame.

Do not use

- on wounds or damaged skin
- if epileptic
- with high blood pressure

When using this product

- avoid contact with the eyes
- do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding,

do not use this product.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: Apply to affected area
not more than 3 to 4 times daily.
- Not recommended for children under 12 years of age.

Inactive ingredients

Anthemis nobilis flower oil, eucalyptus oil, lavender oil, melaleuca leucadendron cajaput oil, organum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, and vitis vinifera (grape) seed oil.

Questions?

1-877-275-7253

Distributed by: SAJE NATURAL WELLNESS 22 East 5th Ave Vancouver, BC Canada V5T 1G8 | saje.com | **1-877-275-7253** | Made in Canada

Pain Release 30 ml

DO NOT USE IF SECURITY SEAL AROUND BOTTLE CAP IS BROKEN OR MISSING.

SKU 10301

Pain Release 10 ml

DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

SKU 431201

Pain Release 6 ml

DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

SKU 442501

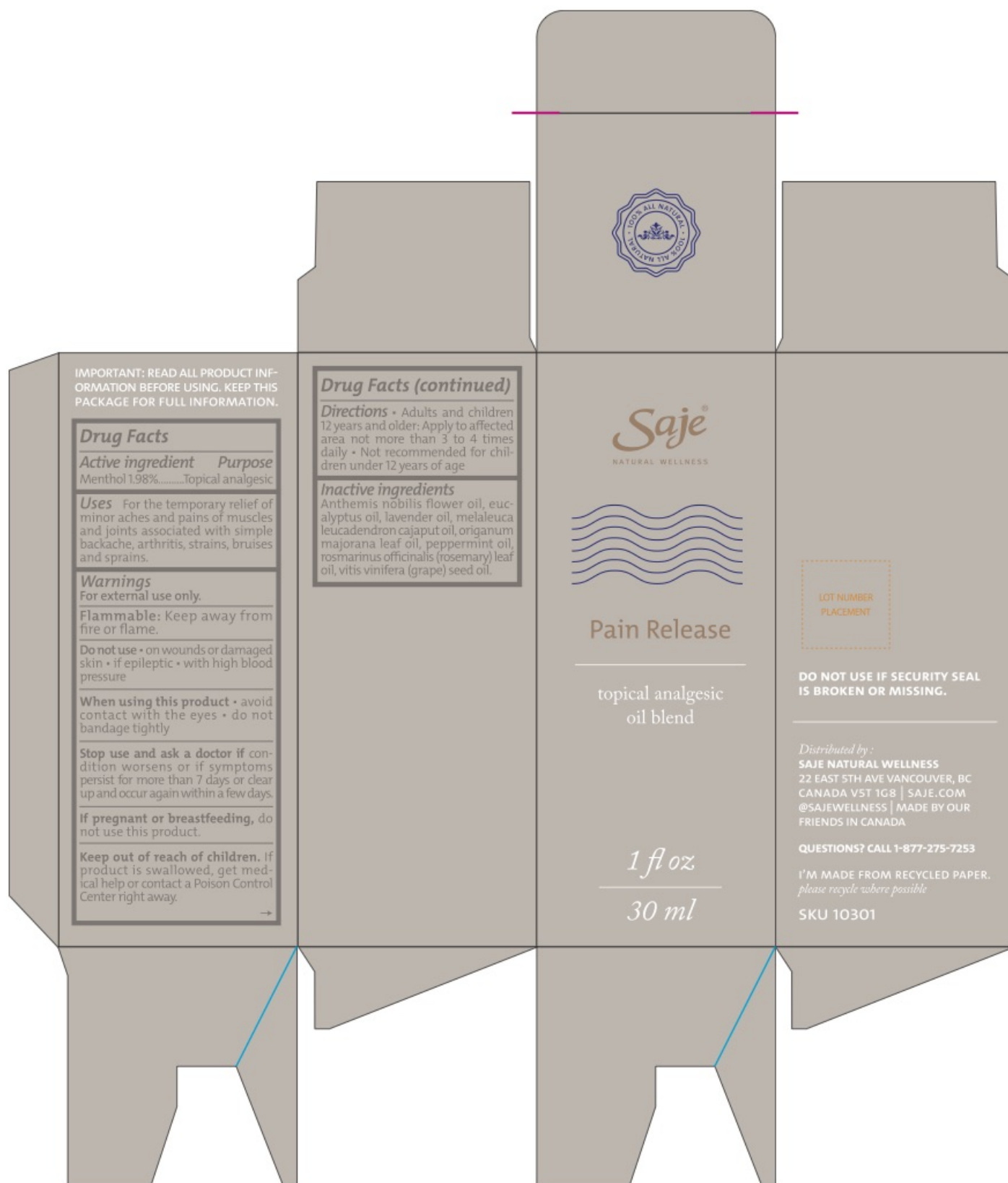
Pain Release Topical Analgesic Oil Blend 30 ml

Saje® Natural Wellness

Pain Release

Topical Analgesic Oil Blend

1 fl. oz. | 30 ml



Pain Release Topical Analgesic Oil Blend 10 ml

Saje® Natural Wellness

Pain Release

Topical Analgesic Oil Blend

0.34 fl. oz. | 10 ml

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS PACKAGE FOR FULL INFORMATION.

| Drug Facts | |
|---|-------------------|
| Active ingredient | Purpose |
| Menthol 1.98% | Topical Analgesic |
| Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains. | |
| Warnings For external use only. | |
| Flammable. Keep away from fire or flame. | |
| Do not use • on wounds or damaged skin • if epileptic • with high blood pressure | |
| When using this product • avoid contact with the eyes • do not bandage tightly | |
| Stop use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days. | |
| If pregnant or breast-feeding, do not use this product. | |
| Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions • Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily • Not recommended for children under 12 years of age | |
| Inactive ingredients Anthemis nobilis flower oil, eucalyptus oil, lavender oil, melaleuca leucadendron cajaput oil, origanum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, vitis vinifera (grape) seed oil. | |



NATURAL WELLNESS



Pain Release
topical analgesic
oil blend



0.34 fl oz
10 ml

DO NOT USE IF SECURITY SEAL IS BROKEN OR MISSING.

Distributed by: SAJE NATURAL WELLNESS 22 EAST 5TH AVE VANCOUVER, BC CANADA V5T 1G8 | SAJE.COM | @SAJEWELLNESS | MADE BY OUR FRIENDS IN CANADA | QUESTIONS? CALL 1-877-275-7253 | I'M MADE FROM RECYCLED PAPER, please recycle where possible

LOT NUMBER
431201

SKU 431201

Pain Release Topical Analgesic Oil Blend 6 ml

Saje® Natural Wellness

Pain Release

Topical Analgesic Oil Blend

0.2 fl. oz. | 6 ml

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING.
KEEP THIS PACKAGE FOR FULL INFORMATION.

Drug Facts

Active ingredient

Menthol 1.98%

Purpose

Topical analgesic

Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

Warnings

For external use only.

Flammable. Keep away from fire or flame.

Do not use • on wounds or damaged skin • if epileptic • with high blood pressure

When using this product • avoid contact with the eyes • do not bandage tightly

Stop use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, do not use this product.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily • Not recommended for children under 12 years of age

Inactive ingredients Anthemis nobilis flower oil, eucalyptus oil, lavender oil, melaleuca leucadendron cajaput oil, origanum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, vitis vinifera (grape) seed oil.

DO NOT USE IF SECURITY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

Distributed by: SAJE NATURAL WELLNESS 22 EAST 5TH AVE VANCOUVER, BC CANADA V5T 1G8 | SAJE.COM | @SAJEWELLNESS | MADE BY FRIENDS IN CANADA | QUESTIONS? CALL 1-877-275-7253 | I'M MADE FROM RECYCLED PAPER. *please recycle where possible*

SKU 442501

LOT NUMBER
PLACEMENT

Saje®
NATURAL WELLNESS



Pain Release

topical analgesic
oil blend



0.2 fl oz

6 ml

PAIN RELEASE

menthol oil

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70983-006 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 17.62 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| CAJUPUT OIL (UNII: J3TO6BUQ37) | |

| | |
|--|--|
| SWEET MARJORAM OIL (UNII: ICH7BE016E) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| ROSEMARY OIL (UNII: 8LGU7VM393) | |
| GRAPE SEED OIL (UNII: 930MLC8XGG) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|--|
| Color | white (clear) | Score | |
| Shape | FREEFORM (oil) | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70983-006-03 | 1 in 1 BOX | 10/16/2016 | |
| 1 | | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |
| 2 | NDC:70983-006-04 | 1 in 1 BOX | 10/16/2016 | |
| 2 | | 10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |
| 3 | NDC:70983-006-05 | 1 in 1 BOX | 10/16/2016 | |
| 3 | | 6 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 10/16/2016 | |

Labeler - Saje Natural Business Inc. (203413380)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------------|---------|-----------|------------------------|
| Natures Formulae Health Products Ltd. | | 241385587 | manufacture(70983-006) |

Revised: 11/2021

Saje Natural Business Inc.